K03 1836

PHILIPS

Philips Medical Systems

AUG 14 2003

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O.Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person:	Lynn Harmer
Telephone No.:	(425) 487-7312
Date Prepared:	June 12, 2003
Device (Trade) Name:	Philips Fresco release 1
Classification Name:	Image processing system, Class II, LLZI, 892.2050

Predicate Device:
The Philips diagnostic X-ray systems Integris H5000 (K984545), Integris Allura (K002016) and the Integris Allura Flat Detector (K031333) systems have the ability to visualize the stent. (basic stent visibility). Philips Fresco release 1, as an add-on to these systems, will improve the visualization of the stent (enhanced stent visibility)

Device description:
The Philips Fresco release 1 will produce an enhanced image of a deployed stent in a coronary artery. To do so, it finds the area of the stent in every image of the Fresco run by finding the radiopaque bullets on the stent delivery catheter. These areas are processed such that the final result over all run images, produces an improved image of the stent area, whereas the distracting peripheral image parts have been blurred.

Indications for Use:
The Philips Fresco release 1, add-on to Philips Integris systems, is intended for use in a cardiovascular and vascular x-ray interventional application, viz. stent placing.

General Safety and Effectiveness

The device and the labeling will comply with the applicable requirements of 21CFR, Subchapter J - Radiological Health, parts 1020.10 and 1040.10
The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety UL 60950 and be classified by Underwriters Laboratories.
The Philips Fresco release 1 will also comply with the ACR/NEMA DICOM digital imaging communication standard.

Conclusion:

The Philips Fresco release 1 does not introduce new indications for use, nor does the use of the device result in any new potential hazard.
Philips Medical Systems considers the Philips Fresco release 1 to be substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2003

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
North America Company
22100 Bothell Everett Highway
P.O. Box 3003
BOTHELL WA 98041-3003

Re: K031836
Trade/Device Name: Philips Fresco release 1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 12, 2003
Received: June 13, 2003

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use statement

510(k) Number (if known): K031836

Device Name: Philips Fresco release 1

Indications for Use:

The Philips Fresco release 1, option to Philips Integris Allura systems, is intended for use in a cardiovascular and vascular x-ray interventional application, viz. stent placing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use .... ✓ OR Over-The-Counter Use .....
(Per 21 CFR 801.109)

(Division Sign-Off)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031836